IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P., Plaintiffs, vs. MYLAN PHARMACEUTICALS INC. Defendant.	C.A. No. 09-184-LPS
MYLAN PHARMACEUTICALS INC., Plaintiff, vs. GALDERMA LABORATORIES INC.; GALDERMA LABORATORIES, L.P.; AND SUPERNUS PHARMACEUTICALS, INC. Defendants.	C.A. No. 10-892-LPS **REDACTED – PUBLIC VERSION**

GALDERMA'S RESPONSIVE BRIEF
REGARDING REMEDY FOR INFRINGEMENT

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for The Research Foundation of State Univ. of New York; New York Univ.; Galderma Labs. Inc.; Galderma Labs., L.P.; and Supernus Pharm., Inc.

OF COUNSEL:

Gerald J. Flattmann, Jr.
Christine Willgoos
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

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I. SUMMARY OF ARGUMENT

Galderma proved at trial that Mylan infringed the valid Chang Patent and Galderma is entitled to relief. Mylan's argument – that it should profit from its infringement of the Chang Patent simply because it was not also found to infringe the Ashley or Amin Patents – is not only extraordinary, it is unprecedented. Mylan's proposed "remedy" is that Galderma hand over its entire Oracea® market and disgorge its past and future profits. Mylan's incredible request flies in the face of decades of statutory and case law precedent precluding generic drug makers from marketing a generic copy of a patented drug prior to patent expiration. The only remedy that can prevent the irreparable harm to Galderma caused by Mylan's infringement is an injunction.

II. GALDERMA IS ENTITLED TO A STATUTORY REMEDY

Galderma is entitled by statute to a change in the effective date of Mylan's ANDA to no earlier than December 19, 2027. *See* 35 U.S.C. § 271(e)(4)(A). Relief pursuant to § 271(e)(4) is not limited by approval or filing date, but applies to ***all*** ANDAs that are submitted under FFDCA § 505(j) where there is an intent to launch a generic drug prior to the expiration of a patent covering that drug. *See* Gal. Br. at 2-5. Mylan's argument that the Court's jurisdiction arose under § 271(a) and not under § 271(e)(2) is mistaken. Mylan's own pleadings ask for relief under § 271(e)(2)(A) by requesting a declaration "that the submission of Mylan's ANDA 90-855 under § 505(j) of the FFDCA does not infringe" the Chang Patent. *See* D.I. 1 (10-892) at 7.

III. GALDERMA IS ENTITLED TO AN EQUITABLE INJUNCTION

A. Galderma Will Suffer Irreparable Harm That Cannot Be Compensated

The irreparable harm that Galderma will suffer in the absence of an injunction is real and indisputable. [redacted]

[redacted]

The self-serving "remedy" that Mylan suggests – [redacted] – is outrageous and unprecedented. In ANDA cases, generic drug makers are invariably precluded from marketing a generic drug upon a finding of infringement of even a single claim of a single patent.[1] Indeed, the statutory remedy of § 271(e)(4)(A) – regardless of whether the Court decides it applies here – is telling. Congress ***mandates*** that where infringement is found based on an ANDA copying a patented drug, the generic not be permitted to market prior to the patent's expiration. Any different result here would undermine the balance that Congress set forth in the Hatch-Waxman amendments. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367-68 (Fed. Cir. 2008).

Moreover, no alleged "reasonable royalty" could possibly compensate Galderma for Mylan's infringement of the Chang Patent. [redacted]

B. The Balance Of Harms Favors An Injunction

In its bid for an extraordinary "remedy," Mylan argues that past harm allegedly caused by the preliminary injunction somehow entitles Mylan to market its drug in the future – even though

[1] Mylan cites cases from other industries and with far different facts, *e.g.*, patentee is willing to license technology (*Advanced Cardiovascular*, *Telecordia Techs.*, *IMX*), patentee is a non-practicing entity that does not commercialize the invention (*eBay*, *Paice*, *z4 Techs.*), patentee is unable to meet critical need in the market created by an injunction (*Bard Peripheral*), and patentee fails to provide any specific evidence of harm not compensable by money damages (*Praxair*). Also inapplicable are Mylan's other cited cases, *e.g.*, generic attempting to block another generic's launch (*Boehringer Ingelheim*), generic seeking expedited review of ANDAs from FDA (*In re Barr Labs.*). None are relevant here.

Mylan cannot claim any future harm from being precluded from infringing a valid patent. Only the future harm to be addressed by the injunction is relevant to issuance of an injunction.

There is no question that Galderma will suffer great harm in the absence of an injunction that is irreparable and cannot be compensated with money damages. *See* Decl. ¶¶ 7-10. Apart from the harms that are specific to the Oracea® market, Galderma will also suffer greater harm overall in the absence of an injunction than Mylan will if an injunction is granted. Oracea® is Galderma's flagship prescription product, [redacted] Gal. Br. Ex. C ¶ 34. In contrast, Mylan is the largest U.S.-based generics manufacturer and the third-largest generics company in the word, sells over 270 generic drugs, has over 170 ANDAs pending in the FDA, and made a gross profit of over $2.2 billion in 2010. *See* Ex. D (highlighting added). Clearly, the balance of harms favors Galderma.

C. The Public Will Not Be Disserved By An Injunction

Mylan's argument that the public will be disserved by an injunction because Mylan will sell its drug at lower cost has already been rejected by Congress, the Federal Circuit and this Court. *See* 35 U.S.C. § 271(e)(4); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005); D.I. 177 (09-184) at 37-38. The public interest in protecting valid patent rights is not outweighed by the public interest in generic drugs. *See* D.I. 177 (09-184) at 37-38.

IV. MYLAN IS NOT ENTITLED TO THE POSTED BOND

In its trial opinion, the Court asked the parties to address the appropriate remedy for Mylan's infringement. Instead, Mylan audaciously requests that the Court ***reward*** its infringement by denying Galderma its patent rights and awarding Mylan the posted bond.

[redacted]

[redacted] Moreover, as the Federal Circuit has not yet considered this case on appeal, the finding of non-infringement of the Ashley Patents (which the Court recognized as "unusual" because it precludes the preferred embodiment (D.I. 278 (09-184) at 47)), may be reversed[redacted][3] – Mylan was well aware that the Chang Patent was about to issue. For example, Mylan's counsel admitted that the Chang Patent "did not come in like a bolt out of the blue. The claims of the patent were allowed back in March." D.I. 241 (09-184) at 9:25-10:1. Thus, Mylan knew, at least three months prior, that the issuance of the Chang Patent was imminent. Mylan also was aware that it infringed the claims of the Chang Patent, and that it could present only weak arguments regarding invalidity.

In these circumstances, Mylan had a strong disincentive to bring its product to the market. Had Mylan launched its product, Mylan would now owe Galderma millions of dollars for its knowing infringement of Chang (which would have continued past the issuance of the patent), which could have been trebled due to its willful infringement. *See* Decl. ¶ 19. And, once Mylan launched at risk, Galderma would have moved for a preliminary injunction, and likely been successful, thus forcing Mylan off the market prior to the expiration of Mylan's 180 days of regulatory exclusivity. Decl. ¶ 17 & n.19. Mylan's argument that it is entitled to money

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[2] [redacted]

[3] To the extent that Mylan claims harm from the preliminary injunction, it was of Mylan's own making. Mylan chose not to present its winning "*in vivo*" argument at the preliminary injunction hearing. Mylan also dropped its motion for reargument. *See* D.I. 245 (09-184) ¶ 3.

damages in the face of a preliminary injunction that saved Mylan from owing Galderma millions of dollars in treble damages and preserved Mylan's 180 days of exclusivity is truly remarkable.

Mylan's claim for damages is unsupported. This Court required Galderma to post a bond of $26 million, which the Court determined was sufficient compensation for a possible 8 months in which Mylan would have been precluded from the market. D.I. 177 (09-184) at 40. [redacted] Moreover, any claim for a bond on a preliminary injunction "must have been suffered during the period in which the bond was in effect." *Glaxo Group Ltd. v. Leavitt*, 481 F. Supp. 2d 434, 437 (D. Md. 2007) (citations omitted). Galderma's bond was posted ***after*** the period of Mylan's alleged harm. D.I. 193 (09-184).

Further, Mylan's alleged stockpiling of its drug was impermissible under statute, which permits manufacture of generic drugs only for the purpose of submitting information to the FDA. *See* 35 U.S.C. § 271(e)(1); *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 396-97 (D. Mass. 1996). To the extent that Mylan stockpiled its generic copy of Oracea®, it owes Galderma damages for its making of the drug claimed in the Chang Patent pursuant to 35 U.S.C. § 154(d) because Mylan had actual notice of the patent application's publication. *See, e.g.*, Ex. H.

Mylan is not entitled to recover any portion of the bond posted by Galderma. To the extent that the Court decides to consider any claim by Mylan for bond, Galderma requests the opportunity for discovery and a hearing on the issue and reserves the right to request damages pursuant to 35 U.S.C. § 154(d). With respect to Mylan's request that the Court deny Galderma's exceptional case claims, that request is premature prior to appeal of this action.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (# 1014)
Maryellen Noreika (# 3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for The Research Foundation of State Univ. of New York; New York Univ.; Galderma Labs. Inc.; Galderma Labs., L.P.; and Supernus Pharm., Inc.

OF COUNSEL:

Gerald J. Flattmann, Jr.
Christine Willgoos
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

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CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused copies of the foregoing document to be served on September 7, 2011, upon the following in the manner indicated:

Richard L. Horwitz, Esquire — *VIA ELECTRONIC MAIL*
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

David S. Steuer, Esquire — *VIA ELECTRONIC MAIL*
Matthew J. Reed, Esquire
Michael D. Nguyen, Esquire
Kirin K. Gill, Esquire
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304

Tung-On (T.O.) Kong, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
One Market Street
Spear Tower – Suite 3300
San Francisco, CA 94105

Lori P. Westin, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
Suite 200
San Diego, CA 92130

/s/ Maryellen Noreika
Maryellen Noreika (#3208)

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2011, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused copies of the foregoing document to be served on September 14, 2011, upon the following in the manner indicated:

Richard L. Horwitz, Esquire — *VIA ELECTRONIC MAIL*
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

David S. Steuer, Esquire — *VIA ELECTRONIC MAIL*
Matthew J. Reed, Esquire
Kirin K. Gill, Esquire
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304

Tung-On (T.O.) Kong, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
One Market Street
Spear Tower – Suite 3300
San Francisco, CA 94105

Lori P. Westin, Esquire — *VIA ELECTRONIC MAIL*
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
Suite 200
San Diego, CA 92130

/s/ Maryellen Noreika
Maryellen Noreika (#3208)